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Dated: December 16, 2010 Signature: _____ (Leneetha L. Dyar)

Docket No.: 046884-5485-00-US-227846 (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Masakazu KATSUMATA et al.

Application No.: 10/583,128

Confirmation No.: 3225

Filed: April 12, 2007

Art Unit: 1645

For: HARMFUL SUBSTANCE EVALUATING METHOD AND HARMFUL SUBSTANCE EVALUATION KIT

Examiner: J. A. Hines

FIRST PRELIMINARY AMENDMENT UNDER 37 C.F.R. 1.115

MS RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY COMMENTS

Concurrently filed herein with a Request for Continued Examination and prior to continued examination, please amend the above-identified application as follows. This filing is in response to the Final Office Action dated June 23, 2010, the period for response to which extends through December 23, 2010, by the concurrently-filed petition for a three-month extension of time and corresponding fee payment.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 11 of this paper.

AMENDMENTS TO THE CLAIMS

Claim 1 (Withdrawn): A toxic substance assay method of assaying a toxic substance present in an aqueous solution sample to be tested, the toxic substance assay method comprising:

a first step of mixing a photosynthetic sample, having a photosynthetic function, with the aqueous solution sample to prepare a test measurement solution, letting the test measurement solution stand for a predetermined standing time, and then after illuminating light onto the test measurement solution for a predetermined illumination time, measuring a light amount of a delayed fluorescence that is emitted;

a second step of letting a comparison measurement solution, prepared by mixing the photosynthetic sample with a comparison sample, stand for the predetermined standing time, and then after illuminating light onto the comparison measurement solution for the predetermined illumination time, measuring a light amount of the delayed fluorescence that is emitted to thereby prepare a comparison measurement result; and

a third step of computing assay values based on the light amounts of delayed fluorescence, respectively acquired in the first step and the second step, and determining a comparison value of the assay values to assay the toxic substance present in the aqueous solution sample,

wherein the assay values are elapsed times of characteristic points in temporal variations of the light amounts of delayed fluorescence acquired in the first step and the second step.

Claim 2 (Currently Amended): A toxic substance assay method of assaying a toxic substance present in an aqueous solution sample to be tested, the toxic substance assay method comprising:

a first step of mixing a photosynthetic sample, having a photosynthetic function, with the aqueous solution sample to prepare a test measurement solution, letting the test measurement solution stand for a predetermined standing time, and then after illuminating light onto the test measurement solution for a predetermined illumination time, measuring a light amount of a delayed fluorescence that is emitted;

a second step of letting a comparison measurement solution, prepared by mixing the photosynthetic sample with a comparison sample, stand for the predetermined standing time, and then after illuminating light onto the comparison measurement solution for the predetermined illumination time, measuring a light amount of the delayed fluorescence that is emitted to thereby prepare a comparison measurement result; and

a third step of computing assay values based on the light amounts of delayed fluorescence, respectively acquired in the first step and the second step, and determining a comparison value of the assay values to assay the toxic substance present in the aqueous solution sample,

wherein the assay values are temporal variations of the light amounts of delayed fluorescence acquired in the first step <u>for the test measurement solution</u> and the second step <u>for the comparison measurement solution,</u>

a Curve value at each measurement point n in the temporal variations is a value obtained by determining a difference of the temporal variations of the light amounts of delayed fluorescence acquired in the first step and the second step, and is determined by (amount of light emitted from the test measurement solution at measurement point n) - (amount of light emitted from the comparison measurement solution at measurement point n), and

the comparison value includes VCurve values determined as ratios of the Curve values ~~obtained by determining differences of the temporal variations of the light amounts of delayed fluorescence respectively obtained from the test measurement solution and the comparison measurement solution~~ divided by the temporal variation of the light amount of delayed fluorescence acquired in the first step or the second step, and

in the third step, the toxic substance present in the aqueous solution sample is assayed based on a time range in which a variation in the VCurve ~~Curve~~ values appears and a positive or negative direction of the variation.

Claim 3 (Original): The toxic substance assay method according to Claim 2, wherein the temporal variation of the light amount of delayed fluorescence acquired in the first step or the second step has a characteristic point, and in the third step, a value obtained by determining a difference of the temporal variations of the light amounts of delayed fluorescence within a predetermined range between one characteristic point and a measurement starting point or another characteristic point is used as the comparison value to assay the toxic substance.

Claim 4 (Canceled).

Claim 5 (Withdrawn): The toxic substance assay method according to Claim 1, wherein in the second step, a standard sample to be compared with is used as the comparison sample, the photosynthetic sample is mixed with the standard sample to prepare a standard measurement solution that is the comparison measurement solution, the standard measurement solution is left to stand for the predetermined standing time, and then after illuminating light onto the standard measurement solution for the predetermined illumination time, the light amount of the delayed fluorescence that is emitted is measured to acquire the comparison measurement result.

Claim 6 (Withdrawn): The toxic substance assay method according to Claim 1, wherein in the second step, another aqueous solution sample is used as the comparison sample and a measurement result, acquired on another test measurement solution that is the comparison measurement solution prepared by mixing the other aqueous solution sample with the photosynthetic sample, is prepared as the comparison measurement result.

Claim 7 (Withdrawn): The toxic substance assay method according to Claim 1, wherein, in the second step, a measurement result, acquired in advance for the comparison measurement solution, is prepared as the comparison measurement result.

Claim 8 (Withdrawn): The toxic substance assay method according to Claim 1, wherein in the first step and the second step, the test measurement solution and the comparison

measurement solution are left to stand for a predetermined standing time with light conditions being varied in each measurement, and

in the third step, a variation of the comparison values according to the light conditions is evaluated.

Claim 9 (Withdrawn): The toxic substance assay method according to Claim 1, wherein the densities of the photosynthetic sample in the test measurement solution and in the comparison measurement solution are within a range of densities that are in a proportional relationship with the light amount of delayed fluorescence.

Claim 10 (Withdrawn): The toxic substance assay method according to Claim 1, wherein in the first step and the second step, the test measurement solution and the comparison measurement solution are homogenized before measuring the light amount of delayed fluorescence.

Claim 11 (Withdrawn): The toxic substance assay method according to Claim 1, wherein the photosynthetic sample includes at least one type of photosynthetic sample, selected from the group consisting of halotolerant algae, alkali-tolerant algae, and acid-tolerant algae.

Claim 12 (Withdrawn): The toxic substance assay method according to Claim 11, wherein the photosynthetic sample is Spirulina.

Claim 13 (Withdrawn): A toxic substance assay method for assaying a toxic substance present in an aqueous solution sample to be tested, the toxic substance assay method comprising:

a preparing step of mixing the aqueous solution sample with a photosynthetic sample, having a photosynthetic function, to prepare a test measurement solution;

a standing step of letting the test measurement solution stand for a predetermined standing time;

a measuring step of illuminating light onto the test measurement solution for a predetermined illumination time and thereafter measuring the light amount of delayed fluorescence that is emitted;

an assaying step of assaying the toxic substance present in the aqueous solution sample based on the light amount of delayed fluorescence acquired in the measuring step; and

an acclimating step, preceding the measuring step and including one of either a dark standby step of subjecting the test measurement solution to a dark standby for a predetermined standby time or a preliminary illuminating step of subjecting the test measurement solution to a preliminary light illumination and to a dark standby for a predetermined standby time.

Claim 14 (Withdrawn): The toxic substance assay method according to Claim 13, wherein in the dark standby step, the predetermined standby time is no less than 30 seconds and no more than 1 hour.

Claim 15 (Withdrawn): The toxic substance assay method according to Claim 13, wherein the ratio of the preliminary light illumination time to the dark standby time in the

preliminary illuminating step is equal to the ratio of the light illumination time to the dark standby time in the measuring step.

Claim 16 (Withdrawn): A toxic substance assay kit for assaying a toxic substance present in an aqueous solution sample to be tested, the toxic substance assay kit comprising:

a photosynthetic sample to be mixed with the aqueous solution sample;

a salt mixture for adjusting the salt concentration and pH of the aqueous solution sample; and

a mixing means that mixes the aqueous solution sample with the photosynthetic sample and with the salt mixture in a separated manner.

Claim 17 (Withdrawn): The toxic substance assay kit according to Claim 16, further comprising a stabilizer for homogenizing the distribution density of the photosynthetic sample.

Claim 18 (Previously Presented): The toxic substance assay method according to Claim 2, wherein in the second step, a standard sample to be compared with is used as the comparison sample, the photosynthetic sample is mixed with the standard sample to prepare a standard measurement solution that is the comparison measurement solution, the standard measurement solution is left to stand for the predetermined standing time, and then after illuminating light onto the standard measurement solution for the predetermined illumination time, the light amount of the delayed fluorescence that is emitted is measured to acquire the comparison measurement result.

Claim 19 (Previously Presented): The toxic substance assay method according to Claim 2, wherein in the second step, another aqueous solution sample is used as the comparison sample and a measurement result, acquired on another test measurement solution that is the comparison measurement solution prepared by mixing the other aqueous solution sample with the photosynthetic sample, is prepared as the comparison measurement result.

Claim 20 (Previously Presented): The toxic substance assay method according to Claim 2, wherein, in the second step, a measurement result, acquired in advance for the comparison measurement solution, is prepared as the comparison measurement result.

Claim 21 (Previously Presented): The toxic substance assay method according to Claim 2, wherein in the first step and the second step, the test measurement solution and the comparison measurement solution are left to stand for a predetermined standing time with light conditions being varied in each measurement, and

in the third step, a variation of the comparison values according to the light conditions is evaluated.

Claim 22 (Previously Presented): The toxic substance assay method according to Claim 2, wherein the densities of the photosynthetic sample in the test measurement solution and in the comparison measurement solution are within a range of densities that are in a proportional relationship with the light amount of delayed fluorescence.

Claim 23 (Previously Presented): The toxic substance assay method according to Claim 2, wherein in the first step and the second step, the test measurement solution and the comparison measurement solution are homogenized before measuring the light amount of delayed fluorescence.

Claim 24 (Previously Presented): The toxic substance assay method according to Claim 2, wherein the photosynthetic sample includes at least one type of photosynthetic sample, selected from the group consisting of halotolerant algae, alkali-tolerant algae, and acid-tolerant algae.

Claim 25 (Previously Presented): The toxic substance assay method according to Claim 24, wherein the photosynthetic sample is Spirulina.

REMARKS

Summary of the Office Action

Claims 2-4 and 18-25 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Schmidt et al. (Biochimica et Biophysica Acta. 1987. Vol. 891:22-27) (hereinafter "Schmidt") in view of Wrobel et al. (J. of Fluorescence, 1998. Vol. 8, No. 3:191-198) (hereinafter "Wrobel").

Summary of the Response to the Office Action

Applicants have amended independent claim 2 to include features from previous dependent claim 4 and also to differently describe embodiments of the disclosure of the instant application. As a result, claim 4 has been canceled without prejudice or disclaimer. Accordingly, claims 1-4 and 5-25 remain currently pending with claims 2-3 and 18-25 currently under consideration.

Rejections under 35 U.S.C. § 103

Claims 2-4 and 18-25 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Schmidt in view of Wrobel. Applicants have amended independent claim 2 to include features from previous dependent claim 4 and also to differently describe embodiments of the disclosure of the instant application. Claim 4 has thus been canceled without prejudice or disclaimer. To the extent that these rejections might be deemed to still apply to the claims as newly-amended, they are respectfully traversed for at least the following reasons.

In the Final Office Action dated June 23, 2010, the Examiner states that "it would have been obvious ... to modify the toxic substance assay method" as taught by Schmidt, and

"incorporate the comparison value includes curve values by determining differences of the temporal variations of the light amounts of delayed fluorescence" as taught by Wrobel, "in order to provide computing assay values based on the light amount of delayed fluorescence acquired by each and determining a comparison value." The Examiner goes on to state that "no more than routine skill would have been required to used the aqueous solution sample is assayed based on a time range in which a variation in the curve value appears and a positive or negative direction of the variation."

In response to the above-described rejection, Applicants have now decided to further amend independent claim 2 of the present application. Applicants respectfully submit that in newly-amended independent claim 2 of the instant application, the following features of the toxic substance assay method of the present invention are clearly described:

> (1) a Curve value at each measurement point n in the temporal variations is determined by (amount of light emitted from the test measurement solution at measurement point n) - (amount of light emitted from the comparison measurement solution at measurement point n);
>
> (2) the comparison value includes VCurve values determined as ratios of the Curve values divided by the temporal variation of the light amount of delayed fluorescence acquired in the first step or the second step; and
>
> (3) in the third step, the toxic substance present in the aqueous solution sample is assayed based on a time range in which a variation in the VCurve values appears and a positive or negative direction of the variation.

Applicants respectfully submit that with regard to the above-described features (1) to (3), for the feature (1), there is a description that "the Curve value at each measurement point n in a temporal variation of the light amount of delayed fluorescence is determined by: (amount of light

emitted from the test measurement solution at measurement point n) - (amount of light emitted from the standard measurement solution at measurement point n) in paragraph [0164] of the specification.

For the above-described feature (2), Applicants respectfully submit that there are descriptions that "a value, determined as a ratio of a value determined as a difference of the temporal variations of the light amounts of delayed fluorescence acquired in the first step and the second step, with respect to the temporal variation of the light amount of delayed fluorescence acquired in the first step or the second step, is used as the comparison value to assay the toxic substance" in previous dependent claim 4 and "it is effective to use VCurve values, each being standardized by being determined as a ratio of a Curve value, which is a value obtained by determining a difference of the temporal variations of the light amount of delayed fluorescence acquired for the test measurement solution and the standard measurement solution, with respect to a light amount of delayed fluorescence acquired for the test measurement solution or the standard measurement solution" as the comparison values in paragraph [0166] of the specification.

For the above-described feature (3), Applicants respectfully submit that there is a description that "[b]ecause the time range in which variations appear and the positive or negative direction of variations differ according to toxic substance, such VCurve values are useful for specifying the types, actions, etc., of the detected toxic substances" in paragraph [0179] of the specification.

Applicants respectfully submit that as particularly described in the specification of the present application, "with the delayed fluorescence emitted from a photosynthetic sample, the

amount of emitted light is high in a time range of early post-excitation time and the amount of emitted light decreases by decay in later time ranges," and thus, "if the time ranges in which the Curve values are computed differ, the magnitudes of the differences of emitted light amounts differ, and there may be cases where it is difficult to evaluate variations in different time ranges."

For the above problem, Applicants respectfully submit that by utilizing the above-described configuration in which the VCurve values are used as the comparison values and the toxic substance is assayed based on a time range in which a variation in the VCurve values appears and a positive or negative direction of the variation, the "evaluation of variations within different time ranges is thereby facilitated." Further, "in comparison to Curve values, variations in different time ranges can be compared readily with VCurve values." Applicants refer to paragraphs [0164] to [0166], and [0179] of the specification of the instant application.

Applicants respectfully submit that these features and effects of the toxic substance assay method of the present invention are neither disclosed, nor even suggested, in the applied Schmidt and Wrobel documents. In particular, Applicants respectfully submit that the VCurve value as a comparison value, determined as a ratio of the Curve value divided by the temporal variation of the light amount of delayed fluorescence acquired in the first step or the second step, is clearly not suggested to any extent in the cited documents.

Accordingly, Applicants respectfully assert that the rejections under 35 U.S.C. § 103(a) should be withdrawn because Schmidt and Wrobel, whether taken separately or combined, do not teach or suggest each feature of newly-amended independent claim 2 of the instant application. As pointed out by MPEP § 2143.03, "'[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.' In re Wilson, 424 F.2d 1382, 1385,

165 USPQ 494, 496 (CCPA 1970)." Since the prior art does not disclose or suggest any of the combinations recited in Applicants' claims, and if anything appears to teach away from the current claim recitations, KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007), Applicants submit that such recited combinations would not have been obvious in view of the applied references of record, whether taken alone or combined in the manner suggested by the Examiner in the Office Action.

Furthermore, Applicants respectfully assert that the dependent claims 3 and 18-25 are allowable at least because of their dependence from newly-amended independent claim 2, and the reasons discussed previously.

CONCLUSION

In view of the above amendment and associated technical remarks, Applicants believe the pending application is now in condition for allowance.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. § 1.16 and 1.17 which may be required, including

any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0573.

This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Dated: December 16, 2010

Respectfully submitted,

By _____

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